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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation for Nominations for Membership on the Secretary's Advisory Committee on Human Research Protections

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health, Office for Human Research Protections.

ACTION: Notice.

AUTHORITY: 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended. The Committee is governed by the provisions of Public Law 92-463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

SUMMARY: The Office for Human Research Protections (OHRP), a program office in the Office of the Assistant Secretary for Health, Department of Health and Human Services (HHS), is seeking nominations of qualified candidates to be considered for appointment as members of the Secretary's Advisory Committee on Human Research Protections (SACHRP). SACHRP provides advice and recommendations to the Secretary, HHS, through the Assistant Secretary for Health, on matters pertaining to the continuance and improvement of functions within the authority of HHS directed toward protections for human subjects in research. SACHRP was established by the Secretary, HHS, on October 1, 2002. OHRP is seeking nominations of qualified candidates to fill three positions on the Committee membership that will be vacated during the 2014 calendar year.

A notice was published in the Federal Register on September 27, 2013, to solicit names of qualified applicants to be considered for appointment to the Committee. The due date for all applications was October 28, 2013. Response to this solicitation notice has been low; a sufficient number of applications has not been received to identify qualified candidates to be considered for appointment. In view of the Government shutdown, it has been determined that more time should be given for individuals to submit applications to be considered for appointment to the Committee. Therefore, this notice is being published in the Federal Register again to allow more time for qualified individuals to submit applications to fill the impending vacancies on SACHRP.

DATES: Nominations for membership on the Committee must be received no later than [INSERT DATE 30 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Nominations should be mailed or delivered to Dr. Jerry Menikoff, Director, Office for Human Research Protections, Department of Health and Human Services, 1101 Wootton Parkway, Suite 200; Rockville, MD 20852. Nominations will not be accepted by e-mail or by facsimile.

FOR FURTHER INFORMATION CONTACT: Julia Gorey, Executive Director, SACHRP, Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852, telephone: 240-453-8141. A copy of the Committee charter and list of the current members can be obtained by contacting Ms. Gorey, accessing the SACHRP website at www.hhs.gov/ohrp/sachrp, or requesting via email at sachrp@osophs.dhhs.gov.

SUPPLEMENTARY INFORMATION: The Committee provides advice on matters pertaining to the continuance and improvement of functions within the authority of HHS directed toward protections for human subjects in research. Specifically, the Committee provides advice relating to the responsible conduct of research involving human subjects with particular emphasis on special populations such as neonates and children, prisoners, and the decisionally impaired; pregnant women, embryos and fetuses; individuals and

populations in international studies; investigator conflicts of interest; and populations in which there are individually identifiable samples, data or information.

In addition, the Committee is responsible for reviewing selected ongoing work and planned activities of the OHRP and other offices/agencies within HHS responsible for human subjects protection. These evaluations may include, but are not limited to, a review of assurance systems, the application of minimal research risk standards, the granting of waivers, education programs sponsored by OHRP, and the ongoing monitoring and oversight of institutional review boards and the institutions that sponsor research.

NOMINATIONS: The OHRP is requesting nominations to fill three positions for voting members of SACHRP. One position will become vacant in March, 2014; two others will become vacant in July. If you submitted a nomination in response to the solicitation request posted in the Federal Register on September 27, 2013, you do not need to resubmit your nomination. Nominations of potential candidates for consideration are being sought from a wide array of fields, including, but not limited to: public health and medicine, behavioral and social sciences, health administration, and biomedical ethics. To qualify for consideration of appointment to the Committee, an individual must possess demonstrated experience and expertise in any of the several disciplines and fields pertinent to human subjects protection and/or clinical research.

The individuals selected for appointment to the Committee can be invited to serve a term of up to four years. Committee members receive a stipend and reimbursement for per diem and any travel expenses incurred for attending Committee meetings and/or conducting other business in the interest of the Committee. Interested applicants may self-nominate. Nominations may be retained and considered for future vacancies.

Nominations should be typewritten. The following information should be included in the package of material submitted for each individual being nominated for consideration: (1) A letter of nomination that clearly states the name and affiliation of the nominee, the basis for the nomination (i.e., specific attributes which qualify the nominee for service in this capacity), and a statement that the nominee is willing to serve as a member of the Committee; (2) the nominator's name, address, daytime telephone number, and the home and/or work address, telephone number, and email address of the individual being nominated; and (3) a current copy of the nominee's curriculum vitae. Federal employees should not be nominated for consideration of appointment to this Committee.

The Department makes every effort to ensure that the membership of HHS Federal advisory committees is fairly balanced in terms of points of view represented and the committee's function. Every effort is made to ensure that individuals from a broad representation of geographic areas, women and men, ethnic and minority groups, and the

disabled are given consideration for membership on HHS Federal advisory committees.

Appointment to this Committee shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, disability, and cultural, religious, or socioeconomic status.

Individuals who are selected to be considered for appointment will be required to provide detailed information regarding their financial holdings, consultancies, and research grants or contracts. Disclosure of this information is necessary in order to determine if the selected candidate is involved in any activity that may pose a potential conflict with the official duties to be performed as a member of SACHRP.

Dated: October 25, 2013.

Jerry Menikoff,

Director, Office for Human Research Protections,

Executive Secretary, Secretary's Advisory Committee

on Human Research Protections.

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